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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,716	04/05/2001	Michael Karpusas	A062 US	4368

7590

05/23/2005

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,716

Applicant(s)

KARPUSAS ET AL

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Amendment filed 02/08/2005 is acknowledged. Claims 34-37 added.
Claims 20, 34-37 are pending.

Applicant's arguments filed have been fully considered and they are deemed to be persuasive-in-part.

Art rejections of claim 20 over the references of Qu et al, Lee et al, or Mayo et al are withdrawn in view of applicant's arguments.

Rejection of claim 20 under 35 U.S.C. 112, second paragraph is withdrawn in view of amendments to the claim.

The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 34-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventors, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection. Claims 20, 34-37 introduce NEW MATTER as they use are directed, in part, to complex comprising " $\alpha_1 \beta_1$ integrin α_1 -I domain". The disclosure of specification is limited to crystals (and use thereof) of fragment 143-340 of α_1 chain of $\alpha_1 \beta_1$ integrin, i.e., of I-domain of α_1 chain. See specification, p. 3-4, and Table 2 (p. 25+). The new claim language "complex comprising $\alpha_1 \beta_1$ integrin α_1 -I domain" (claim 20, line 3) and subsequent language " $\alpha_1 \beta_1$ integrin α_1 -I domain" (claim 20, lines 4,5,7,10,11; claims 34-37), which is clearly different from the terms used in the specification, is understood as a complex of the I domain with $\alpha_1 \beta_1$ integrin. There is no disclosure of such complex in the specification.

Claim 20, 34-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using crystallographic coordinates of I-domain of α_1 chain of rat $\alpha_1 \beta_1$ integrin, does not reasonably provide enablement for using crystallographic coordinates of any complex thereof, or for using crystallographic coordinates of I-domains of $\alpha_1 \beta_1$ integrins of other origins. The rejection is maintained for reasons of record set forth for claim 20, and further in view of the following.

Applicant cites the Drenth reference (used in the rejection) as teaching that "crystal growth is mainly trial and error process". From this, applicant makes conclusion, opposite to Examiner's opinion, that such trial and error would enable finding appropriate conditions for any of I-domains of $\alpha_1 \beta_1$ integrins of other origins. Examiner disagrees. The specification specifically emphasizes difficulties in obtaining crystals of I-domain of α_1 chain of rat $\alpha_1 \beta_1$ integrin, and specifies that all previous attempts of crystallizing has failed. See p. 20, lines 16-18. This, combined with demonstration of uncertainty in the art (exemplified by Drenth reference), demonstrates the need for undue experimentation. Even utilizing the same source of protein and conditions for crystallization, a tiny variation in the way of receiving protein structure information and measurements can cause failure in obtaining useful results.

Applicant points at specification, p. 21, as providing ample guidance on selection of crystallization conditions. Said section of specification however, discusses alternative crystallization conditions for obtaining crystals of the same I-domain obtained from rat $\alpha_1 \beta_1$ integrin, and neither provides guidance on obtaining crystals from I-domains of $\alpha_1 \beta_1$ integrins of other origins, nor even identifies such domains in $\alpha_1 \beta_1$ integrins of other origins.

Applicant further points at references of Qu and Lee as examples of successful crystallization of I-domains. However, as pointed out in

applicant's rebuttal of art rejections over these references, neither Qu, nor Lee teach I domain of the particular integrin, $\alpha_1 \beta_1$ integrin addressed in this invention. Further, neither of the references provides any guidance on obtaining crystals of I-domains from other sources.

Further, with respect to amended claim language directed to " $\alpha_1 \beta_1$ integrin α_1 -I domain", as specification does not provide any written description of such complex (see "new matter" rejection above), specification does not reasonably provide enablement for obtaining and using crystallographic coordinates of a complex of $\alpha_1 \beta_1$ integrin α_1 and I domain.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb